PATENT

Case No. 8627/096

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	Art Unit: 3751
Fred T. Parker	)	
	)	Examiner: A. Ramana
Serial No.: 09/815,567	)	
	)	
Filed: March 23, 2001	)	
	)	
For: INTRODUCER SHEATH	)	
	)	

RULE 1.132 DECLARATION

I, Thomas A. Osborne, declare as follows:

1. I am employed by Cook Incorporated ("Cook") of Bloomington, Indiana, the assignee of the above-referenced United States Patent Application Serial No. 09/815,567 ("the '567 application").

2. I have been employed by Cook in various capacities since 1964. My present title is Senior Vice President of Intellectual Property, Engineering, Training and Development. In the course of my employment, I oversee new product development and production, and new invention disclosures. The areas that I oversee include the development and production of introducer sheaths. At times, I also formulate new invention disclosures related to introducer sheaths.

3. I am an inventor on 30 issued U.S. patents, and numerous additional foreign patents. I am also an inventor on numerous U.S. and foreign pending patent applications.

4 I have reviewed the '567 application, the Office Actions received from the United Stated Patent and Trademark Office ("PTO") and the responses filed on behalf of the applicant, as well as the references cited by the Patent Examiner in support of the rejection of the claims.

5. In Paper No. 17, mailed September 24, 2003, the Examiner stated at page 6: "Appellant's attention is directed to Park et al. who teach the equivalence of a braid or coil for reinforcement of an intravascular device for use in an environment of increasingly small diameters for resistance to kinking (col. 1, lines 9-11 and lines 29-52 and col. 8. lines 29-36)."

6. I disagree with the Examiner's premise that a braid and coil are equivalent for resistance to kinking, and disagree that such a conclusion can be reached from the teaching of the Park patent. It is true that wire braids and wire coils may be considered interchangeable in some instances. However, the Examiner's comments quoted above are much too broad, and do not take into account those instances where the differences between a coil reinforcement and a braid reinforcement can be very significant.

7. With regard to certain properties of a sheath, such as its burst resistance or its crush resistance, the use of a coil reinforcement or a braid reinforcement may be considered generally interchangeable. With regard to certain other properties of a sheath, such as stiffness, pushability or torqueability, a braid reinforcement is superior to a coil reinforcement. On the other hand, when it is desired to maximize the kink resistance of a sheath, a coil reinforcement is superior to a braid reinforcement.

8. The ability to resist kinking is a key factor in the usefulness of an introducer sheath. Such sheaths are frequently used to access tortuous passageways in the vasculature of a patient for the deployment of an interventional device, such as a stent or an angioplasty balloon, that has an outer diameter that is close to the inner diameter of the sheath. During a deployment, a sheath must often traverse a bend of 90° or more. On example of such a bend that must be traversed in an interventional procedure is the bend from the aorta to the renal arteries. This bend is about 90°, and must occur in a radius of about 15 mm. The lumen of the sheath must maintain its round cross-section so that the interventional device can pass through the lumen. Even partial kinking or ovality can prevent such passage, and render the sheath useless.

9. A coil forces the cross section of the inner lumen of a coil-reinforced sheath to remain round by causing the stresses on a bended portion to stretch the material on the outside of the bend and compress the material on the inside of the bend. When a sheath having a braid reinforcement bends, the braid does not allow expansion on the outside of a

curve or compression on the inside of a curve. Since the wall of the braid-reinforced sheath is longitudinally rigid, the stresses produced in a bend force the wall on the outside of the bend and the wall on the inside of the bend toward the central axis of the sheath, thus forcing the lumen to become oval and eventually kink.

10. In order to demonstrate the differences in kink resistance between a coil-reinforced sheath and a braid-reinforced sheath, I performed bending tests on two 10 French (3.3 mm) sheaths. Each tube included an inner liner formed of PTFE and an outer jacket formed of PEBAX. The wall thickness of the tubes was about 0.25 mm. One of the tubes included a stainless steel wire coil reinforcement embedded in the outer jacket, and the other tube included a stainless steel wire braid reinforcement embedded in the outer jacket. Other than the type of reinforcement, the tubes were otherwise identical.

11. During my testing, I bent each tube an equivalent distance to obtain a curve, and photographed the curved portion under a microscope. The photographs are attached hereto as Exhibits A and B. The bends are comparable to bends that would be encountered when attempting to place a stent in the vasculature of a patient.

12. Exhibit A shows the bending of the coil-reinforced tube. As may be observed, the coils spread apart on the outside of the bend, while they move closer on the inside of the bend. This allows the polymer that encases the coil to stretch between the coils on the outside of the curve. Correspondingly, the polymer compresses, or bunches up, on the inside of the curve. This unique property of a coil when compared to a braid allows one to take advantage of polymers with elastic properties, and to avoid kinking.

13. Exhibit B shows the bending of the braid-reinforced tube. As may be observed, the braid does not allow expansion on the outside of the curve or compression on the inside of the curve. As a result, the tube kinks after only slight bending. If one were to use a more elastic material for this tube, the tube would still kink, although it would just take less force to get it to kink.

14. When it is desired to maximize the kink resistance of a sheath, a coil-reinforced sheath is superior to a braid-reinforced sheath. The use of a tube having a braided reinforcement does not improve the ability of the tube to withstand kinking, and in fact, may enhance kinking as shown in Exhibit B. When a sheath has kinked in this manner, the interventional device cannot be passed through the sheath, and the operation has failed.

15. In addition to the foregoing, there are other advantages to the use of a coil reinforcement when compared to a braid reinforcement. When an introducer sheath is to be inserted through tortuous passageways in the vasculature of a patient, it is important that the cross-sectional diameter be maintained as small as possible to accomplish the purposes of the sheath. The cross-sectional diameter of a sheath having a braid reinforcement is greater than the cross-section of a sheath having a coil reinforcement, all other things being equal. This is true whether a flat wire coil is compared to a flat wire braid, or whether a round wire coil is compared to a round wire braid. Another advantage is that an introducer sheath having a coil reinforcement is easier and less costly to manufacture than a sheath having a braid reinforcement. This is due to the fact that when a braid reinforcement is utilized, the ends of the braid must be fused or otherwise adhered to the inner liner of the sheath. Otherwise, the high tensile strength of the braid tends to cause the braid to spring outwardly and not wrap around the liner. In addition, the terminal ends of a braid are prone to fraying if not properly fused or adhered. A wire coil, on the other hand, may simply be compression fitted around the inner liner within the outer tube. Normally, no fusing or bonding of the coil, or its ends, is required.

I declare under penalty of perjury pursuant to the laws of the United States of America that the foregoing is true and correct, and that this Declaration was executed by me on April 28, 2004, at Bloomington, Indiana.

Thomas A. Osborne

Thomas A. Osborne

Exhibit A

flexor1.jpg (640x480x24b jpeg)

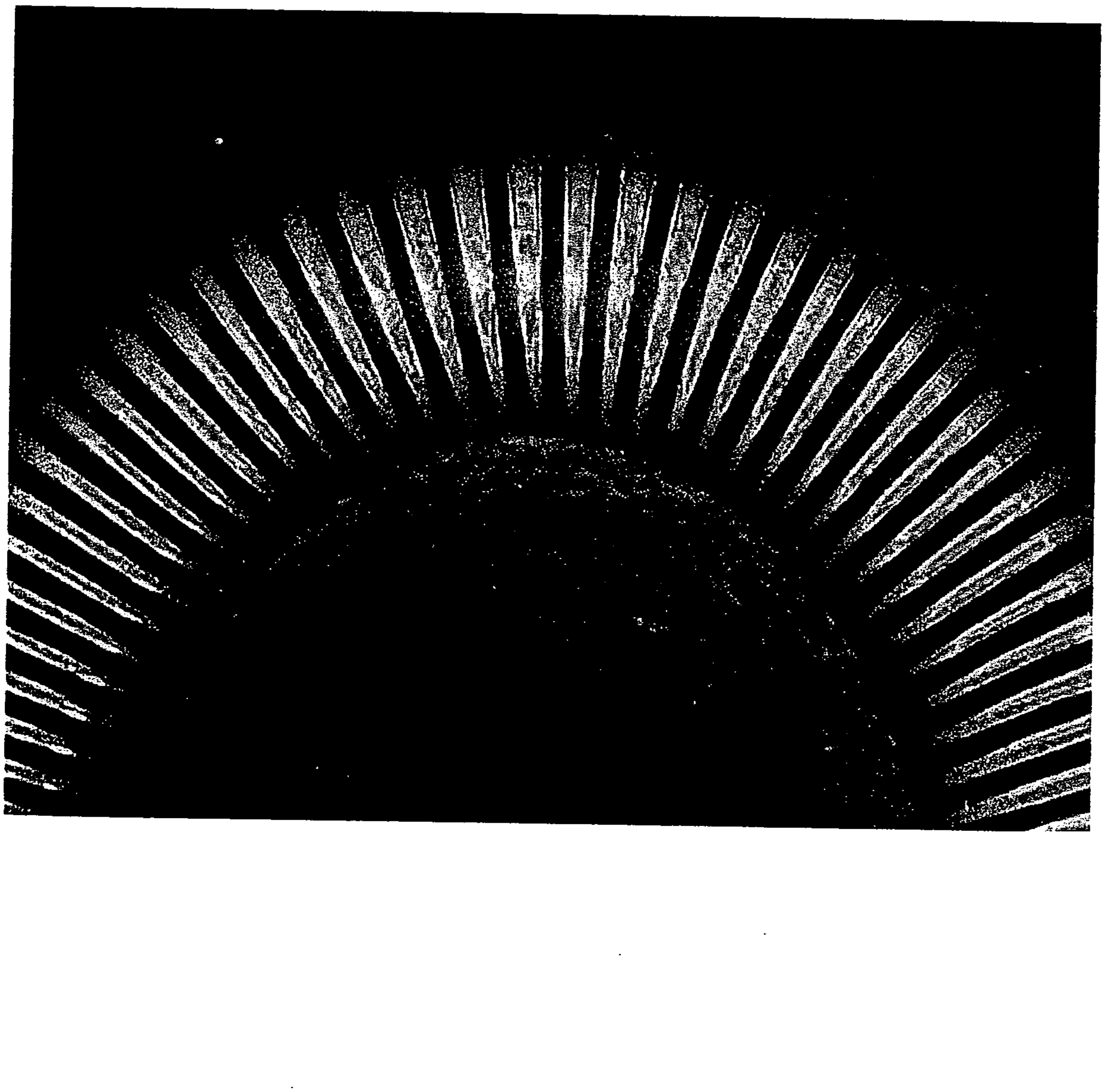

Exhibit B

lumax1.tif (640x480x24b tiff)